

laboratories that presently do have multiple discipline analysis capability, the present invention will substantially reduce equipment cost, space required, manpower and training.

The present invention can also, in most instances, increase the number of tests possible on one analysis device in a particular field. In the field of hematology, for example, the present invention can be programmed to perform analyses such as hematocrit and hemoglobin evaluation, white blood cell count, platelet count, red blood cell indices, red blood cell morphology, five-part differential, reticulocytes evaluation, white blood cell subset analyses, sedimentation rate (ESR), and sepsis detection. As far as is known, no single presently available analysis device can perform all of these analyses.

Another advantage of the present invention apparatus for analyzing a biologic sample is that it does not require substantial dilution or complex fluid handling apparatus. As stated in the Background of the Invention, analyzing whole blood in an impedance or optical flow cytometer has several drawbacks relating to the amount the sample must be diluted and the internal plumbing of the device. The present invention apparatus, on the other hand, requires relatively little or no dilution of the biologic sample, has no internal plumbing, and does not require external calibration. A person of skill in the art will recognize that it is a significant advantage to provide an apparatus with increased reliability. Specifically, the present invention's lack of plumbing eliminates the possibility of downtime attributable to plumbing leaks or that due to a sensor being miscalibrated. The present invention also avoids the expensive service contracts associated with many flow cytometers. Perhaps most importantly, the lack of need for any external calibration removes a large source of potential errors and considerable operational complexity.

Another advantage of the present invention apparatus for analyzing a biologic sample is that it provides faster results for a complete set of tests. In many cases, faster test results mean better patient care because a patient may be evaluated with the results of the tests in hand, rather than the current practice of releasing the patient and requiring a repeat visit if unusual results are encountered. Faster test results also enable the medical office or laboratory

to process more test samples in a given period of time, thereby increasing the number of patients that can be helped and the revenue stream that emanates therefrom.

Another advantage of the present invention is its ability to search a biologic fluid sample for an optimum region(s) to perform a given test. One of the problems common to analyzing biologic samples is that the concentration of constituents within the sample can vary dramatically. Presently available analysis apparatus accounts for the spectrum of constituent concentrations by performing several test iterations. For example if the constituent population within a particular sample is too great, a second iteration of sample must be created by dilution to decrease the number of constituents in a given volume, or vice-versa. This dilution process increases the analysis time and cost, and the probability of error in the analysis. The present invention, in contrast, avoids multiple dilutions by using a biologic fluid container which can segregate constituents and the concentrations of constituents within a chamber, and by having means to know which constituents are where and in what concentration within the chamber for a given analysis. In addition, the present invention is capable of evaluating regions within the sample contained within the chamber comparatively to find a sample region having optimum characteristics for the test(s) at hand. In those situations where it is desirable to evaluate the sample statistically, the present invention can be programmed to evaluate a plurality of regions containing acceptable characteristics and that data collectively analyzed.

Another advantage of the present invention is that it provides a safe means to handle biologic samples. The present invention apparatus includes means for safely handling biologic fluid samples during analysis. Risks associated with handling and disposing of biologic fluid samples are consequently minimized.

These and other objects, features and advantages of the present invention will become apparent in light of the detailed description of the best mode embodiment thereof, as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG.1 is a diagrammatic view of the present invention apparatus for analyzing a sample of biologic fluid quiescently residing within a chamber.

FIG.2 is a diagrammatic view of a container for holding a biologic fluid sample for analysis.

FIG.3 is a cross-sectional view of the container shown in FIG.2.

FIG.4 is a diagrammatic view of an embodiment of the present invention Reader Module which utilizes fluorescence to produce an image.

FIG.5 is a diagrammatic view of another embodiment of the present invention Reader Module which utilizes fluorescence to produce an image.

FIG.6 is a diagrammatic illustration of a sample field between a first chamber wall and a second chamber wall.

BEST MODE FOR CARRYING OUT THE INVENTION

Referring to FIGS. 1 and 2, the apparatus 10 for analyzing a sample of biologic fluid quiescently residing within a chamber includes a Reader Module 12, a Sample Transport Module 14, and a Programmable Analyzer 16. For purposes of this disclosure the terms "analyze" and "analysis" shall be defined as any examination or evaluation of the fluid sample, including but not limited to, the examination of constituents within the sample. The present invention apparatus 10 is preferably used with a particular container 18 for holding a biologic fluid sample for analysis, which is the subject of United States Patent application serial number 09/256,486 and is incorporated herein by reference. Briefly described, the container 18 includes at least one chamber 20, a reservoir 22, a channel 24 (FIG.3) connecting the chamber 20 and the reservoir 22, a valve 26 functionally disposed between the reservoir 22 and the chamber 20, and a label 28. The chamber 20 (see FIG.3) includes a first wall 30 and a transparent second wall 32. In some embodiments, the first wall 30 is also transparent. Fluid sample residing within the chamber 20 may be imaged through one or both transparent walls